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VIA EMAIL (joshua.levine@uspto.gov)

No. of Pages: 10

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Attention: Examiner Joshua Levine, Group Art: 3774

Re: Patent Application of Schwartz
Title: Articular Cartilage Fixation Device and Method
U.S. Serial No.: 10/598,223
Filing Date: August 22, 2006
Our File No.: 3124.006A

Dear Examiner Levine:

Thank you for your willingness to discuss the Office Action mailed October 7, 2011, for the above-referenced application in a phone interview on January 3, 2012, at 10:00AM. I will await your call to the number above. The undersigned attorney requests this interview in hopes of resolving an issue with an ambiguity in the pending Office Action and making some headway toward allowance. To facilitate our discussion, pertinent Figures that may be referred to during the interview are attached hereto as Exhibits.

In order to ensure that our time is used effectively, with this letter, I am advising you of the following issues that I would like to discuss during our interview:

Topic 1) In the Office Action, on Page 2, under the heading enumerated as “1”, the Office states that “[t]his office action is responsive to the amendment filed on 02/28/2011. As directed by the amendment: claims 35, 36 and 46 have been amended...”. In the amendment of 2/28/2011, independent Claim 35 was amended, *inter alia*, to recite that a distal end of the flexible member is “mechanically locked” to a section of the cartilage replacement material at an attachment point. The amendments to Claim 1 that were introduced in the 2/28/2011 amendment are attached hereto as Exhibit 1 for reference. Before the amendment, as shown in Exhibit 1, Claim 35 recited that the flexible member was “configured to attach” to a section of the cartilage replacement material at an attachment point. Thus, the 2/28/2011 amendment specifically amended “configured to attach” to “mechanically locked”.

However, in the “Claim Rejections” section where the rejection of Claim 35 is discussed (Page 3), the Office Action states that Hayhurst discloses, *inter alia*, “said flexible member being configured to attach to said section of replacement material at an attachment point 68 (figure 14...)”. [Emphasis added]. The Office Action thereby fails to fully consider the claim amendments of 2/28/2011 and is improper. This failure to answer the substance of Applicant’s previous response renders the Office Action incomplete as to all matters, as is required by 37 C.F.R. § 1.104(b). Further, MPEP § 707.07(f) states that “[i]n order to provide a complete application file history and to enhance the clarity of the prosecution history record, an examiner must provide clear explanations of all actions taken by the examiner during prosecution of an application” (emphasis added). “Where the applicant traverses any rejection, the examiner should, if he or she repeats the rejection, take note of the applicant’s argument and answer the substance of it” (Id., emphasis added). “The examiner must address all arguments which have not already been responded to in the statement of the rejection” (MPEP § 707.07(f), Examiner Note 1). In the present case, the outstanding Office Action recites old claim language which is no longer pending in the application, and thereby fails to address the new claim language introduced in the 2/28/2011 amendment. As such, the pending Office Action failed to address Applicant’s clear traversal.

Further, regarding dependent Claims 58-61, which further define the “mechanically locked” claim language, the Office Action cites Fallin for teaching or suggesting the claimS. Therefore, it is unclear whether the “mechanically locked” amendment was considered, and if it was considered, it is unclear whether Hayhurst or Fallin is cited against the claim language. Failure to

specifically respond to amended claim language renders the Office Action arbitrary and capricious, and therefore invalid under the Administrative Procedure Act (5 U.S.C. § 706), a standard to which all Actions by the USPTO must adhere (See *Dickenson v. Zurko*, 527 U.S. 150 (1999)).

The Applicant respectfully requests that the Examiner address the substance of Applicant's claim amendments, specifically the "mechanically locked" language of Claim 35, in the next Office Action. Further, Applicant respectfully requests that at least because the outstanding Office Action is incomplete under 37 C.F.R. § 1.104(b) and does not meet the requirements of MPEP § 707.07(f), the finality be of the pending Office Action be withdrawn.

Topic 2) As it is unclear in the Office Action whether the Office deems Hayhurst and/or Fallin as teaching or suggesting that a distal end of the flexible member is "mechanically locked" to a section of the cartilage replacement material at an attachment point, the undersigned attorney would like to discuss the reasoning behind the amendment and how the amendment distinguished the claims over the cited art.

Further, on Pages 6-7 of the "Remarks" section of the 2/28/2011 response and amendment, the agent that submitted the response noted "[a]s discussed in the [May 4, 2011] phone interview, Examiner Levine suggested that the attachment point of the flexible member to the replacement section may distinguish the claimed invention from the cited art." The undersigned attorney would like to revisit this distinguishing feature of the invention.

Topic 3) The undersigned attorney would also like to discuss the current rejections to Claims 35 and 46 under the combination of Hayhurst and Fallin. Specifically, it is unclear how one of ordinary skill in the art could combine the teachings of Hayhurst and Fallin to arrive at the claimed invention, especially without impermissible hindsight reasoning.

Topic 4) The undersigned attorney would also like to discuss the pending rejections to several dependent claims. It is the Applicant's view that at least some of the dependent claims distinguish over the cited art, and that the rejections to these claims are therefore improper. The dependent claims which the undersigned attorney would like to discuss, and their pertinent claim language, is as follows:

- A. Claim 38 – When the sliding device **“is tensioned about said flexible member”** the cartilage replacement material is retained.
- B. Claims 43 and 47 – The stopping member of the sliding device **“is engageable with”** the cartilage replacement material.
- C. Claim 54 – The **“proximal looped end [is] positioned through the sliding device”** and **“upon tensioning of the proximal looped end, the two distal loops corresponding slide through the anchor”**.
- D. Claims 58 and 60 – Mechanically locked comprises **“tied”**.
- E. Claims 59 and 61 – Mechanically locked comprises **“attached to a base attached to the section of cartilage replacement material”**.

Topic 5) The undersigned attorney would also like to discuss other aspects of the invention that distinguish over the cited art. Specifically, aspects that are either not directly or explicitly claimed will be discussed. These aspects may be more clearly claimed or introduced via amendment to further distinguish the claimed invention over the cited art. These aspects are as follows:

- A. The anchor being positioned on one side of the cartilage replacement material, and **the sliding member being positioned on an opposing side of the cartilage replacement material.**
- B. The flexible members are threaded through the anchor at least twice to form at least two pulley mechanisms, **each pulley mechanism defining two members** extending from the anchor and **at least one member of each pulley mechanism traversing the cartilage replacement material.**
- C. The flexible members are threaded through the anchor at least twice to form at least two pulley mechanisms and **at least one loop therebetween**, and the **sliding member being formed about at least two members of said at least one loop.**
- D. The flexible members are threaded through the anchor at least twice to form at least two pulley mechanisms and **a loop therebetween**, and the **loop is enlarged** to locate **and retain** the section of cartilage replacement material in the defect site.

- E. The sliding member is located at the proximal end of the flexible member **both before and after** the section of cartilage replacement material is located and retained in the defect site.
- F. The **portion of the flexible member located between the distal end and the sliding member** traverses through the section of cartilage replacement material **at least three times**.
- G. The **length of the flexible member between the sliding member and the distal end remains the same both before and after** the section of cartilage replacement material is located and retained in the defect site.

Thank you for the opportunity to discuss these matters.

Very truly yours,

HESLIN ROTHENBERG FARLEY & MESITI P.C.



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EXHIBIT A

35. (*Currently amended*) A surgical device for repairing cartilage tissue at a defect site in a patient, said surgical device comprising:

a biocompatible anchor shaped to sit within tissue at the defect site and retain a section of cartilage replacement material in the defect site;

a biocompatible flexible member traversing through said section of cartilage replacement material multiple times, a distal end of said flexible member configured to attach mechanically locked to said section of cartilage replacement material at an attachment point and ~~thread~~ a proximal end of said flexible member threaded through said anchor at least twice to form at least two pulley mechanisms; and

a sliding device about said flexible member, wherein, when in use, the at least two pulley mechanisms are actuated to translate the sliding device distally along said flexible member to a position proximate said section of cartilage replacement material to locate and retain said section of cartilage replacement material in the defect site.

EXHIBIT B

FIG. 17

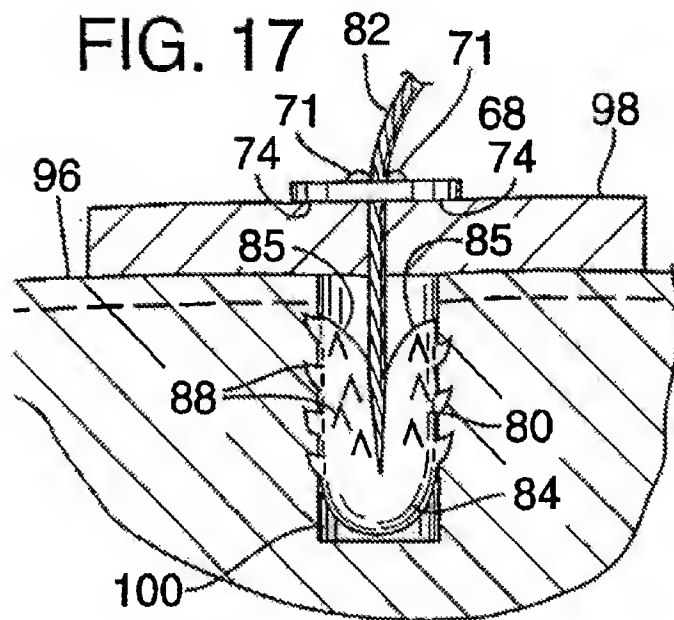


FIG. 19

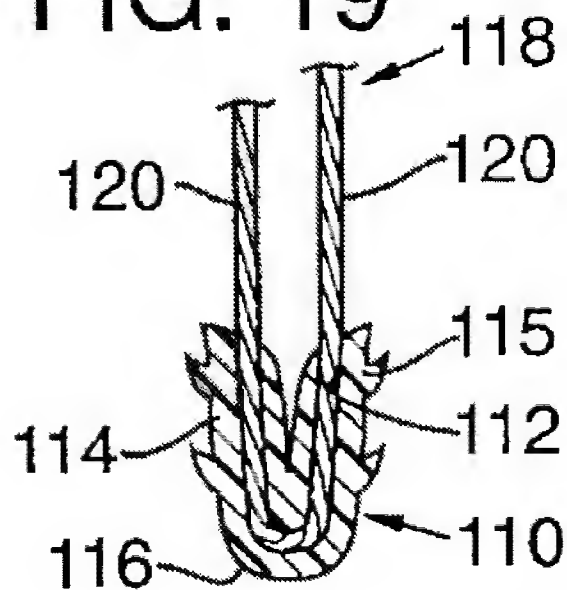


EXHIBIT C

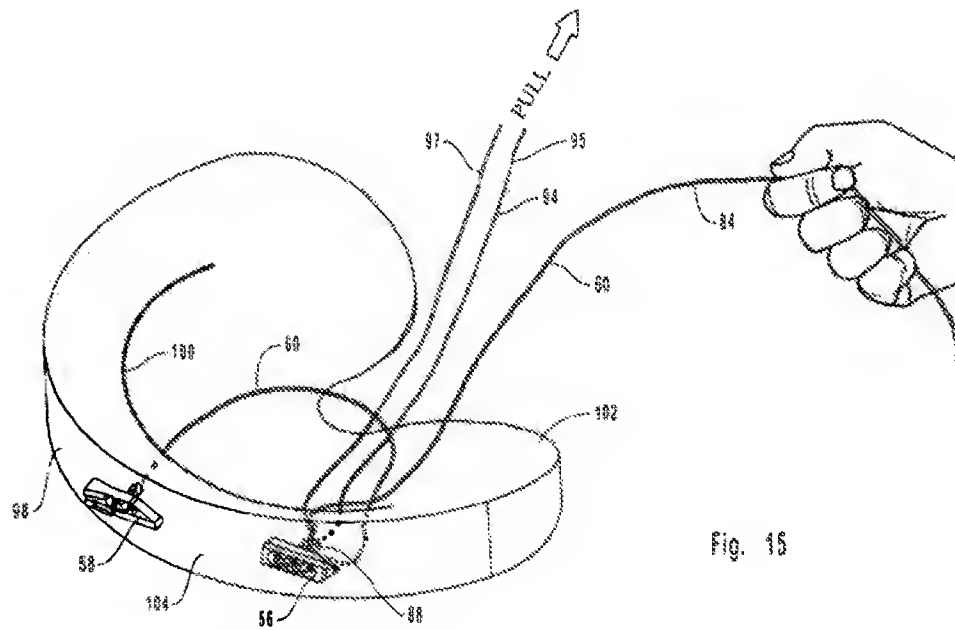
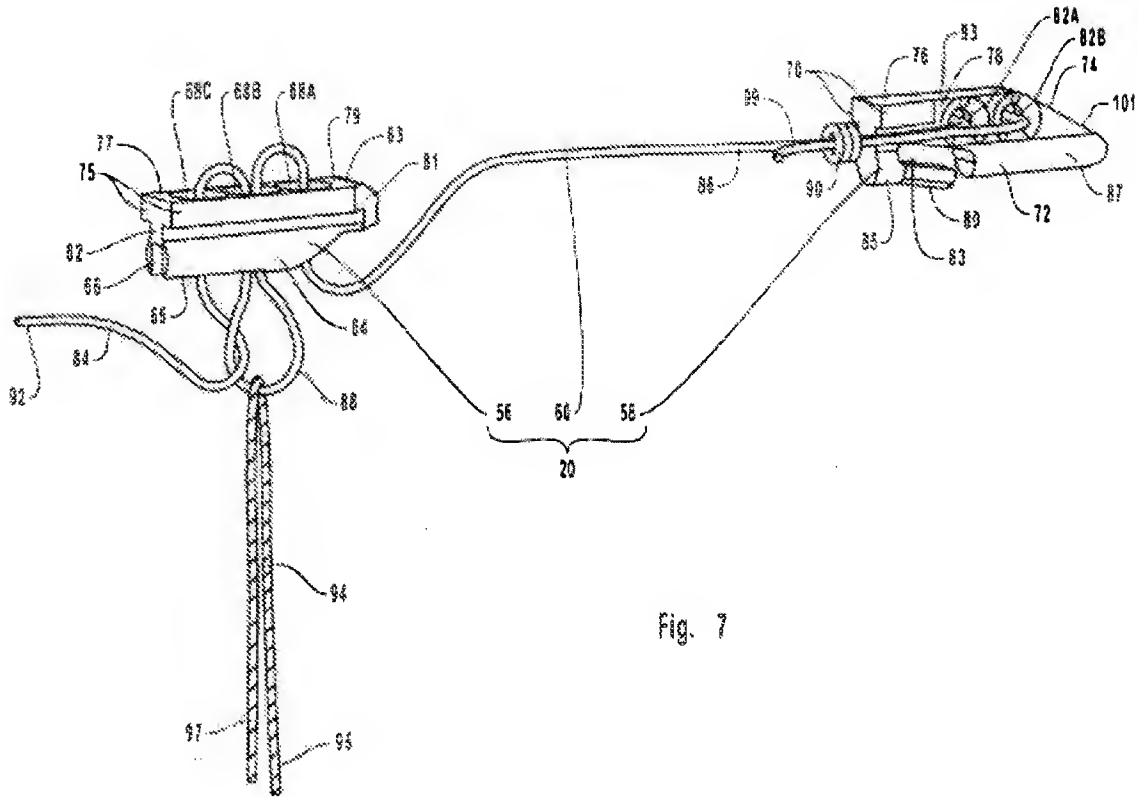


EXHIBIT D

